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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary

Application No.

09/617,459

Applicant(s)

ST. GOAR ET AL.

Examiner

LoAn H. Thanh

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/6/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Since all the claims are directed to one embodiment the election requirement of the has been withdrawn.

All claims will be examined.

An action on the merits will now follow.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the stylet, the actuator/ shaping mechanism and the blood flow device for maintaining circulation of oxygenated blood must be shown or the feature(s) canceled from the claim(s). (see claims 8-9 and page 18, line10) No new matter should be entered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "116 " – the 2nd inflation opening of balloon (110) . see page 19, last paragraph. . A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The lengthy specification has not been checked however, not checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The disclosure is objected to because of the following informalities:

On page 12, line 10, "mm2" should be corrected to "mm²".

Reference numeral "68" has been designated "tube" (see page 16) and "guidewire" (see page 17).

Applicant refers to fig. 3 on page 17 , line 20. Only fig. 3a and 3b are disclosed.

Applicant is requested to update the status of all the U.S. serial numbers which have been incorporated by reference (i.e. if they have been issued a patent no.).
Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is a lack of support for the language of a shaping mechanism or actuator in the specification. It is the position of the Examiner that the shaping mechanism is the pull wire(s) of the stylet as disclosed on page 18. Applicant

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has support for the shaft to be preferably 25-75 cm on page 5 of the specification, however there is not support for the shaft to be at least 25 cm as claimed in claim 4. Applicant is requested to put the same language in the specification. Further, there is a lack of support for a blood flow device positioned downstream from the occlusion member for maintaining circulation of oxygenated blood in the arterial system. It is unclear what structure this blood flow device encompasses due to a lack of description in the specification.

Claim Objections

Claim 13 is objected to because of the following informalities: "mm2" should be "mm²". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is unclear what the blood flow device is without any description of it in the specification. It is unclear what structure this blood flow device encompasses and it is unclear whether this blood flow device is a

tube, an opening , another balloon or whether it is another embodiment not elected and not shown.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3,5,6,7,8,11-12,14-17,19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sweezer et al. (U.S. Patent No. 5,478,309).

Sweezer et al. disclose a cardioplegia catheter comprising a shaft, having a proximal and distal end, an opening (36 or 11 or 14 etc.) near the distal end, an inner lumen fluidly connect to the port at the proximal end and an occlusion member (6 or 8 or 27). Sweezer et al. teach a sealing device such as a purse string suture for sealing the catheter at the puncture site. (col. 24, lines 10-29). Sweezer et al. further teach a

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guiding catheter such as a guidewire (col. 19, lines 21-22) or stylet (col. 24, lines 29-35) for positioning the catheter and a source of cardioplegia fluid. See figures especially 1-7, 9-13, 21-27, 38-39, for the delivery port, opening (14 or 11 or 91 etc.) and lumen. With respect to placement of the device in the areas of the heart, Sweezer et al. is capable of being configured for those locations.

With respect to claim 20, the occlusion member is considered to be (8) and the blood flow device is considered to be (6) as best understood and broadly interpreted by the Examiner. See fig. 9.

Claims 1, 4-6, 11-13, 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyd et al. (U.S. Patent No. 5,558,644).

Boyd et al. disclose a cardioplegia catheter (20) comprising (see fig. 4a-c) a shaft (122) with a distal (124) and proximal end (126) and an opening (132) near the distal end, a port at the proximal end (126), an inner lumen (128) for delivering cardioplegia fluid which connects the port and the opening (132) and an occlusion member. Boyd et al. further teach the shaft to be at least about 50 cm in length, a guiding device introducer sheath and the inner lumen having a cross-sectional area of no less than 4 mm^2 . Boyd et al. teach the inner lumen to deliver the cardioplegia fluid at a flow rate of at least 200ml/min with a pressure less than 300mm Hg. . With respect to placement of the device in the areas of the heart, Boyd et al. is capable of being configured for those locations.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sweezer et al. (U.S. Patent No. 5,478,309) in view of Brennen et al. (U.S. Patent No. 5,439,006).

Sweezer et al. disclose the invention substantially as claimed. Sweezer et al. teach a guidewire or stylet for placing the cardioplegia catheters in the area to be used. However, Sweezer et al. is silent to the stylet having an actuator at the proximal portion. Brennen et al. teach a steerable stylet having an actuator at the proximal end of the stylet for guiding a catheter to a desired location in a patient's cardiovascular system analogous art of placing catheters. Brennen et al. teach the stylet to be shaped by the pull wires connected to an actuator in the handle of the proximal end of the stylet. (See abstract, figs. 1-3, col. 6, lines 53-65 and col. 7, lines 2-29 of Brennen et al.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stylet of Sweezer et al. with the actuator, shaping mechanism of Brennen et al. in order to provide a guidance system into the tortuous pathways of the cardiovascular system.

Conclusion

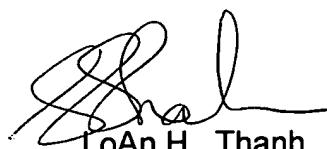
Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is

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(703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'LoAn H. Thanh', is positioned above the printed name and title.

LoAn H. Thanh
Examiner
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LT
August 25, 2002